

U.S.C. § 112, First Paragraph

Claims 1, 4, 8, 14, 25, 28, 34, 43, 46, and 58, are rejected under 35 U.S.C. § 112 first paragraph as allegedly not providing enablement for all substances which might conceivably fall within the scope of the claimed invention.

The standard for determining whether the specification meets the enablement requirement was set forth in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which addressed the question: is the experimentation needed to practice the invention undue or unreasonable? In In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir. 1988), the Court held that the specification was enabling with respect to the claims at issue and found that “there was considerable direction and guidance” in the specification; there was “a high level of skill in the art at the time the application was filed,” and “all of the methods needed to practice the invention were well known.” 858 F.2d at 740, 8 USPQ2d at 1406. The Wands Court further listed eight factors for enablement analysis:

- 1) The breadth of the claims;
- 2) The nature of the invention;
- 3) The state of the prior art;
- 4) The level of one of ordinary skill;
- 5) The level of predictability in the art;
- 6) The amount of direction provided by the inventor;
- 7) The existence of working example; and
- 8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Here, considering all the Wards’ factors, particularly applicant’s detailed disclosure, coupled with the state of the art at the time of patent filing, applicants respectfully traverse the rejection on the basis that the claims are fully enabled for their entire scope.

The specification provides detailed experiments illustrating the practice of the present invention. For example, the specification discloses the details of how nitric oxide plays an important role in blood flow and metabolism (See page 3, lines 12-30). A list of substances that increases nitric oxide is disclosed (page 5, lines 17-33). The specification continues to disclose details of how insulin activity affects muscle metabolism (page 3, line 31 to page 4, line 23). Substances that increase insulin activity are listed (page 5, line 27 to page 6, line

4). Furthermore, the specification discloses a list of substances that increases nitric oxide production by stimulating insulin levels in the circulation (page 5, lines 22-26). It is known in the art at the time patent filing the measurement of nitric oxide and insulin activity and standard methodologies exist. See, for example, U.S. Pat. Nos. 5,885,842 and 5,891,735. A skilled artisan would be able to determine whether a given substance can increase the nitric oxide production or mimics and/or enhances insulin activity.

It is well settled that an applicant needs not make or test all embodiments of the invention in order to meet the requirement of 35 U.S.C. §112. So long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement of 35 U.S.C. §112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. In re Angstadt, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

The Examiner has already conceded that the specification enables the invention for the list of substance disclosed (page 5, lines 17-33, page 6, lines 1-4). Since the specification provides detailed instructions of how to identify and make/use of related substances which possess the ability to increase nitric oxide or mimics and/or enhances insulin activity in general, Applicants respectfully submit that the invention is fully enabled for the full scope of the claims.

For the foregoing reasons, Applicant believes that these grounds for the rejections should be negated and withdrawal of rejections is earnestly solicited.

IV. The Rejection of Claims Under 35 U.S.C. § 102(e) or In the Alternative, Under 35 U.S.C. § 103(a) As Obvious Over Schneider et al.

Claims 1, 2, 8 and 9:

The Examiner alleges that claims 1, 2, 8, and 9 are unpatentable as being anticipated

by Schneider et al. U.S. 5,902,892 [sic]¹ under 35 U.S.C. §102(e) or 35 U.S.C. §103(a).

Claims 2 and 9 are cancelled and the rejection against these claims should be mooted. The applicants request reconsideration of the withdrawn of the remaining claims.

35 U.S.C. §102(e):

Applicants reserve the right to swear behind the cited reference.

Applicants respectfully submit that the cited reference disclose patentable distinct subject matter as in the present invention. To be an anticipatory prior art, the cited reference must contain all the elements listed in the present application. See, e.g., Hybritech, Inc. v. Monoclonal antibodies, Inc. 802, F.2d 1367, 1379, 231 USPQ 81 (Fed.Cir., 1986). Also, the cited reference must be a complete and operable invention capable of being put into practical operation. See, e.g., Atlas Powder Co. v. E.I. du Pont de Nemours and Co., 221 USPQ 426, (N.D. Texas 1983), *aff'd*, 224 USPQ 409 (Fed. Cir. 1984). In another words, the cite reference must teach one of ordinary skill how to practice the invention (i.e., enabling) (See MPEP 2121).

Applicant respectfully submits that Schneider's '829 patent is directed solely to a method of administering a medicament or nutritional formulation in patients undergoing surgery for the amelioration of micro-circulatory hypo-perfusion, and /or the treatment or prophylaxis of hypoperfusion-reperfusion injury. The '829 patent does not disclose a food supplement that increases nitric oxide production in the body of a normal subject. The '829 patent also fails to provide an enabling disclosure regarding how to make/use of a composition directed to a food supplement intended for use in increasing lean mass and strength.

35 U.S.C. § 103(a):

Regarding the alternative 35 U.S.C. §103 rejection, Applicants respectfully submit that the Examiner fails to satisfy the initial burden to show a *prima facie* case of obviousness. To

¹Applicants believe the corrected U.S. Pat. No. is 5,902,829 ('829 patent).

establish a *prima facie* case of obviousness, there must be i) some suggestion or motivation; 2) a reasonable expectation of success; and iii) teach or suggest all the claim limitations. (MPEP §706.02(j)).

The '829 patent and its claims are solely directed to methods for modulating microcirculation by administering medicament in patients undergoing surgery or patients suffering from hypo-perfusion-reperfusion injury. There is no express or inherent suggestion or motivation to apply the medicament in a normal subject, let alone to increase lean muscle mass and strength. Given the significant physiological differences between patients of hypo-perfusion-reperfusion injury and a normal subject, there is no reasonable expectation of success that medicament disclosed in Schneider may work in increasing muscle mass/size of a normal subject. Finally, the Schneider's disclosure does not contain each and every claim limitation (see above discussion). Accordingly, the Examiner fails to satisfy the initial burden and withdrawal of the 103 rejection is earnestly solicited.

Claims 1, 8, 9, 13-17, and 58-61:

The Examiner alleges that claims 1, 8, 9, 13-17 and 58-61 are unpatentable as being obvious over Schneider et al. U.S. 5,902,892 under 35 U.S.C. §103(a).

Claims 1, 9, 17, 60 and 61 are cancelled and the rejections against these claims should be mooted. The applicants request reconsideration of the withdrawn of the remaining claims.

The Examiner alleges that Schneider et al. (referring to the '829 patent and not the '892 patent; see discussion above) teaches a composition containing arginine and amino acids, such as whey protein that provides a source of nitrogen/nitric oxide. Similar to the reasons as stated above, Applicants respectfully submit that the Examiner fails to satisfy the initial burden to show a *prima facie* case of obviousness. There is no explicit nor inherent teaching of using arginine and amino acids in normal subjects other than patients undergoing elective major abdominal surgery, major trauma and trauma that often associated with high morbidity and mortality (column 9, lines 6-19). There is no showing of either a reasonable expectation of

success or teaching of each and every limitation of the present claims. Accordingly, the Examiner fails to satisfy the initial burden and withdrawal of the 103 rejection is earnestly solicited.

The Examiner's allegation that one of ordinary skill in the art would have been motivated to modify Schneider (page 5, line 5 of 12/04/00 Office Action) is nothing more than "an invitation to experiment" or "obvious to try", both of which are improper standards for 103 rejection.

V. The Rejection of Claims Under 35 U.S.C. § 102(b) or In the Alternative, Under 35 U.S.C. § 103(a) As Obvious Over Uiterwaal et al.

Claims 1, 2, 8, 13-17, 58 and 59:

The Examiner alleges that claims 1, 2, 8, 13-17, 58, and 59 are unpatentable as being anticipated by Uiterwaal et al. U.S. 4,710,387 (the '387 patent) under 35 U.S.C. §102(b) or 35 U.S.C. §103(a).

Claims 2 and 17 are cancelled and the rejections against these claims should be mooted. The applicants request reconsideration of the withdrawn of the remaining claims.

35 U.S.C. §102(b):

The Uiterwaal's '387 patent does not disclose a food supplement that increases nitric oxide production in the body of a normal subject. Accordingly, it fails to be an anticipatory prior art because it lacks all the elements listed in the present application and it fails to teach one of ordinary skill how to practice the invention (i.e., enabling) as required.

35 U.S.C. § 103(a):

Applicants respectfully submit that the Examiner is improper to cite Uiterwaal under 103 rejection as it represents a non-analogous art. Two criteria are required for determination of non-analogous art: First, if the reference is within the field of the inventor's endeavor. Second, if it is not, whether the reference is reasonably pertinent to the particular problem with which the inventor was involved. See, e.g., In re Wood, 202 USPQ 171, 174 (CCPA 1979).

The '387 patent is related solely to nutritional supplement preparation for pregnant and breast-feeding women based on milk constituents. In sharp contrast, the present invention teaches food supplement that increases nitric oxide and insulin activity to increase muscle mass and strength in a normal subject, preferably an athlete. The Uiterwaal's art is certainly not in the same field of endeavor. Merely because it relates to supplement does not make the Uiterwaal's patent belong the same field of endeavor as the present invention.

Furthermore, the '387 patent does not reasonably pertinent to the particular problem with which the present inventor was involved. It is well recognized that there are significant differences in physiology between a pregnant or breast-feeding woman and a normal subject. A nutrient supplement for pregnant/breast feeding women has little, if any, direct relevancy to the problem relating to enhancing lean muscle mass and strength in normal individuals.

VI. The Rejection of Claims Under 35 U.S.C. § 102(e) or in the Alternative, Under 35 U.S.C. § 103(a) As Obvious Over Portman et al.

The Examiner alleges that claims 1-4, 8, 13-18, 25-28, 34-37, 43-46, and 58 are unpatentable as being anticipatory by Portman under 35 U.S.C. § 102(e) or in the alternative as being obvious under 35 U.S.C. §103(a).

Claims 2, 26, 35 and 44 are cancelled and the rejections against these claims should be mooted. The applicants request reconsideration of the withdrawn of the remaining claims.

35 U.S.C. §102(e):

The Portman's '236 patent is directed to a nutritional composition for optimizing muscle performance during exercise and for enhancing muscle repair and recovery after exercise. The specification further disclose that such composition must be in a carbohydrate/ protein ratio of 2.8 to 4.2. Portman fails to disclose a food supplement that increases nitric oxide production in the body of a normal subject. Portman fails to disclose substances that increases nitric oxide production by stimulating insulin levels in the circulation. Portman does not disclose nitric oxide may increase nitrogen retention. Portman simply fails to address any aspects

relating to enhancement of muscle size and/or strength in an individual. Accordingly, it fails to be an anticipatory prior art because it lacks all the elements listed in the present application; and its disclosure is far from enabling (i.e., Portman fails to teach one of ordinary skill how to practice the present invention.

35 U.S.C. § 103(a):

Applicants respectfully submit that the Examiner fails to satisfy the initial burden to show a *prima facie* case of obviousness. There is no explicit nor inherent teaching of using arginine and amino acids in enhancing lean muscle size and strength in normal subjects. While Portman teaches using protein and arginine with carbohydrate to stimulate insulin level (column 17, lines 25-27), it teaches away using protein alone in general to stimulate insulin, let alone any teaching in nitric oxide production to enhance muscle size/strength. For example, Portman states “more protein can be less effective, as too much protein can have an adverse effect on gastric emptying. . . The challenge is how to gain the benefits of protein without the negative effect on gastric emptying. When the aforementioned OR² ratio of carbohydrate to protein is 4. . the insulin stimulating action of protein does not appear to interfere with the essential rehydration phase.” (column 17, lines 37-51. There is no showing of a reasonable expectation of success in using protein alone (except a restricted ratio with carbohydrate of 4) in stimulating insulin, much less in stimulating nitric oxide and further in enhancing muscle size/strength. This single prior art also fails to teach each and every limitation of the present claims. Accordingly, the Examiner fails to satisfy the initial burden and withdrawal of the 103 rejection is earnestly solicited.

VII. The Rejection of Claims Under 35 U.S.C. § 103(a) As Obvious Over Portman in View of Doi et al., Kim et al., Droge et al., Larner et al. and Jableck et al.

The Examiner alleges that claims 1-61 are unpatentable as being obvious over Portman in view of Doi et al., Kim et al., Droge et al., Larner et al., and Jableck et al. under 35 U.S.C. §103(a).

Claims 2, 6, 9, 17, 26, 30, 35, 39, 44, 60 and 61 are cancelled and the rejections against these claims should be mooted. The applicants request reconsideration of the withdrawn of the remaining claims.

In determining obviousness, it is incumbent upon the Examiner to demonstrate the teachings from the prior art suggest the claimed subject matter to one of ordinary skill in the art. In re Bell, 991 F.2d. 781, 26 USPQ 1529 (Fed.Cir. 1993). Individual references cannot be employed as a mosaic to recreate a facsimile of the claimed invention. W.L. Gore & Assoc., Inc. v. Garlock, Inc., 772 F.2d 1540, 1551, 220 USPQ 303, 312 (Fed. Cir. 1983). Simply piecing together the prior art does not support a *prima facie* obviousness. It is also improper to use non-analogous art as the basis for 103 rejection (see above).

Doi expressly teaches that “glucomannan depressed insulin activity” (abstract, lines 5-6). Such teaching is sharp contrary to Portman which teaches “protein/arginine stimulates insulin.” The Examiner’s assertion to combine Doi with Portman is simply illogical. One of ordinary skill in the art would not combine the Portman and Doi as they lead to conflicting effect on insulin activity, a recognized key factor in muscle rebuilding.

Kim discloses that saponin from Panax ginseng on free radical-induced pulmonary endothelial injury in intact lungs. Contrary to the Examiner’s assertion that Kim teaches that saponins derived ginseng promote release of nitric oxide in the body, Kim has never measured the nitric oxide activity. One of ordinary skill in the art would recognize that the Kim’s statement regarding saponin and nitric oxide is nothing more than a speculation. There is not inherent or express motivation/suggestion to combine Portman and Kim; especially in light of the fact that they clearly are non-analogous art.

Droge fails to disclose nitric oxide and its relationship with insulin. Droge fails to teach any supplements that cause release of nitric oxide and enhancement of lean muscle size/strength. The deficiency in Droge’s teaching cannot be cured by Portman.

Larner represents another example of non-analogous art as it solely relates to a dietary supplement for therapeutic treatment of patients who are insulin-resistant type II diabetes. In fact, it amounts to a “teaching away” reference as one skilled artisan would not simply use the Larner’s supplements in a normal subject in an attempt to enhance muscle mass size/strength.

While Jablecki teaches inositol incorporation into phosphatidyl-inositol in rat muscle, it teaches the effects of unilateral tenotomy on muscle hypertrophy. Jablecki further teaches that simultaneous spinal section abolish the incorporation activity. Not only Jablecki is a non-analogous art as it solely relates to neural contribution on hypertrophy in rat, the reference alone or in combination fails to suggest/motivate to meet the claim limitation of the present invention with any expectation of success.

In sum, it is clear the Examiner hindsight reconstructs the present invention by pick and choose among isolated disclosures in the prior art in order to deprecate the claimed invention. Applicants respectfully remind the Examiner that the proper standard for obviousness determination is listed in MPEP §706.02(j) where it states that the Examiner has to satisfy the initial burden to show a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, there must be i) some suggestion or motivation; 2) a reasonable expectation of success; and iii) teach or suggest all the claim limitations. The cited references, alone or in combination, fail all these elements. Accordingly, the Examiner fails to satisfy the initial burden and withdrawal of the 103 rejection is earnestly solicited.

CONCLUSION

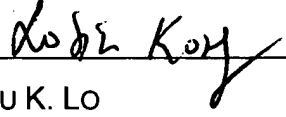
In view of the foregoing remarks, Applicant respectfully submits that all the pending claims are in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is urged to telephone the undersigned at (212) 908-6018.

AUTHORIZATION

The Commissioner is authorized to charge any required fees which may be due, or credit any overpayment, to Deposit Account No. 11-0600.

RESPECTFULLY SUBMITTED
KENYON & KENYON

DATED: MAY 30, 2001

BY: 
SIU K. LO
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

CLAIMS 2, 6, 9, 17, 26, 30, 35, 39, 44, 48, 60 AND 61 HAVE BEEN CANCELLED.

CLAIMS 1, 3, 4, 5, 7, 8, 10, 13, 14, 15, 16, 18, 20, 21, 22, 23, 24, 25, 27, 28, 29, 31, 32, 33, 34, 36, 37, 38, 40, 41, 42, 43, 45, 46, 47, 49, 50, 51, 53, 54, 55, 56, 57, 58 HAVE BEEN AMENDED AS FOLLOWS:

1. (Amended) A food supplement comprising L-arginine, a source of amino acids, and at least one [a] substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine and folic acid], and, a source of amino acids].
3. (Amended) The [A] food supplement according to claim 1 [2] wherein the substance is ginseng.
4. (Amended) A food supplement which comprising L-arginine, a source of amino acids and at least one [a] substance which can enhance and/or mimic insulin activity selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol [and a source of amino acids].
5. (Amended) The [A] food supplement according to claim 4 wherein the substance is glucomannan.
7. (Amended) The [A] food supplement according to claim 4 [6] wherein the substance is myo-inositol.
8. (Amended) A food supplement comprising L-arginine, a source of amino acids, and at least one [a] substance which increases nitrogen retention in the body selected from the group consisting of glucomannan, glycosidal saponins, ginseng, glutamine, methionine and leucine [and a source of amino acids].
10. (Amended) The [A] food supplement according to claim 8 [9] wherein the substance is glucomannan.
13. (Amended) The [A] food supplement according to any one of claims 1 to 12 wherein the source of amino acids is selected from the group

- consisting of WPI 97, Whey Peptides, WPC 80, ION EXCHANGE, lactoferrin, and whey protein.
14. (Amended) The [A] food supplement comprising L-arginine, whey protein and at least one [a] substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine and folic acid [and, whey protein].
15. (Amended) The [A] food supplement according to claim 14 wherein the whey protein is WPI 97, Whey Peptides, WPC 80, or ION EXCHANGE whey protein.
16. (Amended) The [A] food supplement according to claim 14 wherein the whey protein is a combination of two or more of WPI 97, Whey Peptides, WPC 80, or ION EXCHANGE whey protein.
18. (Amended) The [A] food supplement according to claim 17 wherein the substance is ginseng.
20. (Amended) The [A] food supplement according to claim 19 comprising 150mg to 1500mg glycosidal saponins; about 100mg to 2000mg myo-inositol; and 25mg to 2000mg glucomannan.
21. (Amended) The [A] food supplement according to claim 19 comprising 50mg to 500mg glycosidal saponins; about 200mg to 1000mg myo-inositol; and 50mg to 1000mg glucomannan.
22. (Amended) The [A] food supplement according to claim 19 comprising 100mg to 500mg glucomannan.
23. (Amended) The [A] food supplement according to claim 19 comprising about 50mg glycosidal saponins.
24. (Amended) The [A] food supplement according to any one of claims 19 wherein the amino acids comprise whey protein.
25. (Amended) A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of a supplement comprising L-arginine, a source of amino acids and at least one [a] substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, and folic acid [and a source of amino acids].
27. (Amended) The [A] method according to claim 25 [26] wherein the substance is ginseng.

28. (Amended) A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of a supplement comprising L-arginine, a source of amino acids and at least one [a] substance which can enhance and/or mimic insulin activity selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol [and a source of amino acids].
29. (Amended) The [A] method according to claim 28 wherein the substance is glucomannan.
31. (Amended) The [A] method according to claim 28 [30] wherein the substance is myo-inositol.
32. (Amended) The [A] method according to claim 31, wherein the supplement is administered to the diet of the athlete on a daily basis.
33. (Amended) The [A] method according to claim 32, wherein the food supplement is mixed with water to provide a liquid drink.
34. (Amended) A method for increasing muscle mass and / or strength of an individual, comprising administering to the diet of the athlete of an effective amount of [a supplement] L-arginine, a source of amino acids, and at least one [a] substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, and folic acid [and a source of amino acids].
36. (Amended) The [A] method according to claim 34 [35] wherein the substance is ginseng.
37. (Amended) A method for increasing muscle mass and/or strength of an individual comprising administering to the diet of the athlete an effective amount of a supplement comprising L-arginine, a source of amino acids and at least one [a] substance which can enhance and/or mimic insulin activity selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol [and a source of amino acids].
38. (Amended) The [A] method according to claim 37 wherein the substance is glucomannan.
40. (Amended) The method according to claim 37 [39] wherein the substance is myo-inositol.

41. (Amended) The [A] method according to claim 40 wherein the supplement is administered to the individual on a daily basis.
42. (Amended) The [A] method according to claim 41 wherein the food supplement is mixed with water to provide a liquid drink.
43. (Amended) A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of supplement comprising L-arginine, whey protein and at least one [a] substance which increases nitric oxide production in the body selected from the group consisting of glycosidal saponins, ginseng, N-acetyl cysteine, and folic acid [and whey protein].
45. (Amended) The [A] method according to claim 43 [44] wherein the substance is ginseng.
46. (Amended) A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete an effective amount of supplement comprising L-arginine, whey protein, and at least one [a] substance which can enhance and/or mimic insulin activity selected from the group consisting of N-acetyl cysteine, myo-inositol, cis-inositol, epi-inositol, allo-inositol, muco-inositol, neo-inositol, scyllo-inositol, d-chiro-inositol, l-chiro-inositol, and d-pinitol [and whey protein].
47. (Amended) The [A] method according to claim 46 wherein the substance is glucomannan.
49. (Amended) The [A] method according to claim 46 [48] wherein the substance is myo-inositol.
50. (Amended) The [A] method according to claim 46 [48], wherein the supplement is administered to the athlete on daily basis.
51. (Amended) The [A] method according to claim 50, wherein the food supplement is mixed with water to provide a liquid drink.
53. (Amended) The [A] method according to claim 52 wherein the supplement comprises 150mg to 1500mg glycosidal saponins; about 100 mg to 2000 mg myo-inositol; and 25mg to 2000mg glucomannan.
54. (Amended) The [A] method according to claim 52 wherein the supplement comprises 50mg to 500mg glycosidal saponins; about 200mg to 1000mg myo-inositol; and 50mg to 1000mg glucomannan.

55. (Amended) The [A] method according to claim 52 wherein the supplement comprises 100mg to 500mg glucomannan.
56. (Amended) The [A] method according to claim 52 wherein the supplement comprises 50mg glycosidal saponins.
57. (Amended) The [A] method according to any one of claims 52-56 wherein the amino acids comprises whey protein.
58. (Amended) A food supplement comprising L-arginine, a source of amino acids and at least one substance [a component] which increases nitric oxide production in the body, the food supplement being in powder or granular form.